UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

EUNICE BUNING,	)	
	)	
Plaintiff,	)	CIVIL ACTION NO.: 1:19-cv-80
v.	)	
	)	
ZIMMER, INC. and	)	JURY TRIAL DEMANDED
ZIMMER HOLDINGS, INC. , n/k/a	)	
ZIMMER BIOMET HOLDINGS, INC.	)	
	)	
Defendants.	)	
_____	)	

COMPLAINT

COMES NOW, Plaintiff, EUNICE BUNING, by and through her counsel, hereby sues ZIMMER, INC. and ZIMMER HOLDINGS, INC., n/k/a ZIMMER BIOMET HOLDINGS, INC. an Indiana Corporation, (collectively, referred to as "Zimmer").

NATURE OF THE ACTION

1. This is a products liability action seeking damages for personal injuries sustained by Plaintiff, EUNICE BUNING arising from use of a defective product designed, manufactured, labeled, and distributed, or otherwise placed into the stream of commerce by Defendants and/or each of them for injuries arising out of the M/L Taper® Hip Prosthesis Femoral Stem with a VerSys® Femoral Head (hereinafter "Zimmer Hip System").

2. Defendant Zimmer designed, manufactured, marketed and supplied to doctors a total hip arthroplasty system known as the M/L Taper® Hip Prosthesis Femoral Stem with a cobalt chromium VerSys® Femoral Head. The M/L Taper® Hip Prosthesis Femoral Stem was designed to be implanted with either (1) a cobalt-chromium femoral head or (2) a ceramic femoral head.

3. The Zimmer Hip System utilized with a cobalt-chromium femoral head created an unreasonable risk of harm to Plaintiff.

4. The unreasonable risk of pain, swelling, metallosis, trunnionosis, adverse local tissue reaction, tissue and/or muscle necrosis, joint instability, elevated metal ion levels, and/or the need for early revision surgical intervention, whether from corrosion, micromotion, fretting or some other mechanism, renders the Zimmer Hip System with a metal cobalt-chromium femoral head a defective product.

5. The selection and implantation of the Zimmer Hip System by Plaintiff's surgeon, was a result of the misinformation, marketing, sales, promotion and direction by Zimmer.

JURISDICTION & VENUE

6. This is a lawsuit over defective hip implant components designed, marketed, manufactured, promoted and sold by Defendants ZIMMER INC., and ZIMMER HOLDINGS, INC., n/k/a ZIMMER BIOMET HOLDINGS, INC. (hereafter collectively "Zimmer").

7. Plaintiff is and was at all times relevant, a citizen and resident of the County of Ottawa, state of Michigan. Plaintiff underwent right total hip replacement on August 28, 2009. At that time, the Zimmer Hip System manufactured, designed, distributed, and warranted by Defendants was implanted into Plaintiff. Plaintiff's surgeon, medical staff, and other healthcare providers met or exceeded the standard of care applicable to the hip replacement surgery.

8. ZIMMER, INC. is and was at all times relevant, a foreign corporation, organized under the laws of Delaware with principal place of business located in Warsaw, Indiana.

9. ZIMMER HOLDINGS, INC. n/k/a ZIMMER BIOMET HOLDINGS, INC. is a foreign corporation organized under the laws of Delaware, with its principal place of business located in Warsaw, Indiana. ZIMMER, INC. is a subsidiary of ZIMMER HOLDINGS, INC.

ZIMMER distributes their products throughout the United States and internationally.

10. ZIMMER INC. and ZIMMER HOLDINGS, INC. n/k/a ZIMMER BIOMET HOLDINGS, INC. are hereinafter collectively referred to as "Zimmer". "Zimmer" includes and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents and representatives and any and all other persons acting on behalf of Defendant ZIMMER, INC. and Defendant ZIMMER HOLDINGS, INC. n/k/a ZIMMER BIOMET HOLDINGS, INC.

11. The defective Zimmer Hip System was sold to and implanted into Plaintiff's right hip on August 28, 2009.

12. The Defendants acted jointly and severally.

13. At all times relevant hereto, the Defendants developed, tested, manufactured, advertised, promoted, marketed, sold and/or distributed the defective Zimmer Hip System, throughout the United States, including within the State of Michigan, and, specifically including to Plaintiff's implanting physician or practice group, or to the hospital where the Zimmer Hip System was implanted.

14. Zimmer designed, manufactured, fabricated, marketed, packaged, advertised, distributed, and sold the Zimmer Hip System devices throughout the world, including in the State of Michigan.

15. Zimmer knowingly markets to, and derives income from, patients in the State of Michigan from the sale of the Zimmer Hip System.

16. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different States, and the amount in controversy exceeds the sum or value of $75,000,

exclusive of interest and costs.

17. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendants did (and does) business within the State of Michigan and have had continuous and systematic contacts with the State of Michigan, and they have consented to jurisdiction in the State of Michigan. Upon information and belief, Defendants also advertised in this District, made material omissions and representations in this District and breached warranties in this District.

TAG ALONG ACTION

18. This is a potential tag-along action and, in accordance with 28 U.S.C. § 1407, it should be transferred to the United States District Court for the Southern District of New York for inclusion in *In re: Zimmer M/L Taper Hip Prosthesis or M/L Taper Hip Prosthesis With Kinectiv Technology and VerSys Femoral Head Products Liability Litigation*, MDL No. 2859 (Hon. Paul A. Crotty).

GENERAL FACTUAL ALLEGATIONS

A. Background on the Zimmer Defendants

19. Founded in 1927, Zimmer is the third largest orthopedic device manufacturer in the United States.

20. Zimmer tests, studies, researches, designs, formulates, manufactures, inspects, labels, packages, promotes, advertises, markets, distributes, and sells reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. Zimmer's related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures. Zimmer also has a limited array of sports medicine products. Zimmer's primary customers include orthopedic surgeons,

musculoskeletal surgeons, neurosurgeons, oral surgeons, dentists, hospitals, distributors, healthcare dealers and, in their capacity as agents, healthcare purchasing organizations or buying groups. These customers range from large multi-national enterprises to independent healthcare practitioners.

21. In 2008, the U.S. hip and knee replacement market was valued at $6.7 billion, with the hip replacement market contributing thirty-eight percent of the market at roughly $2.5 billion dollars.

22. According to Zimmer's 2008 Annual 10-K Report, Zimmer was number one in global market share for reconstructive hip components. In the period ending December 2008, Zimmer reported $1.2795 billion in hip component sales. Zimmer's total 2008 sales exceeded $4 billion.

23. According to Zimmer's 2016 Annual 10-K Report, in the period ending December 2016, Zimmer reported $1.868 billion in hip component sales. Zimmer's total 2016 sales exceeded $7.684 billion.

B. Hip Replacement Surgery and Artificial Hip Devices

24. The hip joint, scientifically referred to as the acetabulofemoral joint, is the joint between the femur (the thigh bone) and the acetabulum (the hip socket) of the pelvis, and its primary function is to support the weight of the body in both static (*i.e.*, standing) and dynamic (*i.e.*, walking or running) postures.

25. Total hip replacement, also known as total hip arthroplasty, is a surgical procedure in which the patient's hip joint is resurfaced and replaced with an artificial implant which is designed to replicate the human anatomy – that is, the relatively simple ball and socket structure of the human hip joint.

26. Hip replacement surgery traditionally consists of several stages. First, the orthopedic surgeon removes the top of the femur, or thighbone. Next, the orthopedic surgeon reams or hollows out a portion of the top of the femur and inserts a metal femoral stem into the remaining femur bone. The surgeon then uses a hammer to strike an artificial "ball" or femoral head typically made of a metal alloy, stainless steel or ceramic onto the top end of the femoral stem. Next, the surgeon reams out the patient's natural acetabulum and inserts an acetabular cup in the resulting space. In some hip implant systems, a metal, plastic or ceramic liner is then fitted inside the acetabular cup. Finally, the surgeon fits the ball-shaped femoral head into the liner of the acetabular cup where it should move easily, without friction or pain to the patient.

27. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications for total hip replacement include rheumatoid arthritis, femoral head fracture, avascular necrosis, arthritis associated with Paget's disease of the bone, and ankylosing spondylitis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only after other non-surgical options, such as pain medications and physical therapy, have failed.

28. Total hip replacement is a common medical procedure performed on more than 420,000 patients in the U.S. each year. In 2010, the prevalence of total hip and total knee replacement in the total U.S. population was 0.83% and 1.52%, respectively. Prevalence was higher among women than among men and increased with age, reaching 5.26% for total hip replacement and 10.38% for total knee replacement at eighty years of age. These estimates correspond to 2.5 million individuals (1.4 million women and 1.1 million men) with a total hip replacement and 4.7 million individuals (3.0 million women and 1.7 million men) with a total knee replacement in 2010.

C. Modularity in Hip Implant Design and Mechanically Assisted Crevice Corrosion

29. Traditional hip replacement devices consisted of a monobloc stem, which was a femoral stem with a single neck/head option all constructed from a single piece of metal. Monobloc stems made restoring a patient's leg length and femoral offset challenging and increased the component inventory at healthcare facilities.

30. The concept of "modularity" was introduced into the design of hip prostheses and has become increasingly common in the last two decades. Modularity aimed to provide surgeons with additional versatility when attempting to restore normal biomechanical function in patients.

31. Modularity can be exhibited at the juncture between the femoral head and the trunnion of the femoral stem. The trunnion is the tapered top end of the femoral stem upon which the femoral head is affixed. The trunnion has a taper angle that is wider at the proximal than distal end. The bore (or hollow portion of the inside of the ball) of the femoral head has a corresponding taper angle which is wider at the distal than proximal end. When the two components are affixed together, the corresponding taper angles allow for an interference fit between the femoral head and femoral stem. The contact area between the inside of the bore of the femoral head (the female taper surface) and the trunnion of the femoral stem (the male taper surface) is called the taper interface.

32. The taper interface is designed to prevent motion when assembled; however, studies have demonstrated that micromotion can develop over time at a malfunctioning taper interface resulting in articulation of the bore of the femoral head against the trunnion of the femoral stem to the degree that the oxide layer existing between the components is gradually worn down resulting in metal debris wearing off the component parts.

33. Fluid from the joint can also enter a malfunctioning taper interface particularly with femoral stems which employ a trunnion with microgrooves.

34. Historically, manufacturers have produced femoral stems with a trunnion that has either a smooth or microgrooved surface finish. A femoral stem trunnion with microgrooves has a rough surface area which looks like microscopic screw threads or the ridges of a vinyl record. The microgrooves are designed to allow for a better interference fit with ceramic femoral heads. However, when fluid enters the taper interface, the microgrooves create a crevice-like environment which facilitates a crevice corrosion process whereby the underlying metal corrodes and releases metal ions, particularly cobalt and/or chromium, off the components.

35. Whether caused by fretting or corrosion, the release of metal debris and/or ions can result in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurological (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications.

36. Studies have further shown that metal debris produced from a corrosive process is more biologically toxic and therefore harmful to humans than metal particulates produced from a fretting process alone.

37. The process by which metal ions and debris buildup in the soft tissues of the hip joint and blood is often generally referred to as metallosis.

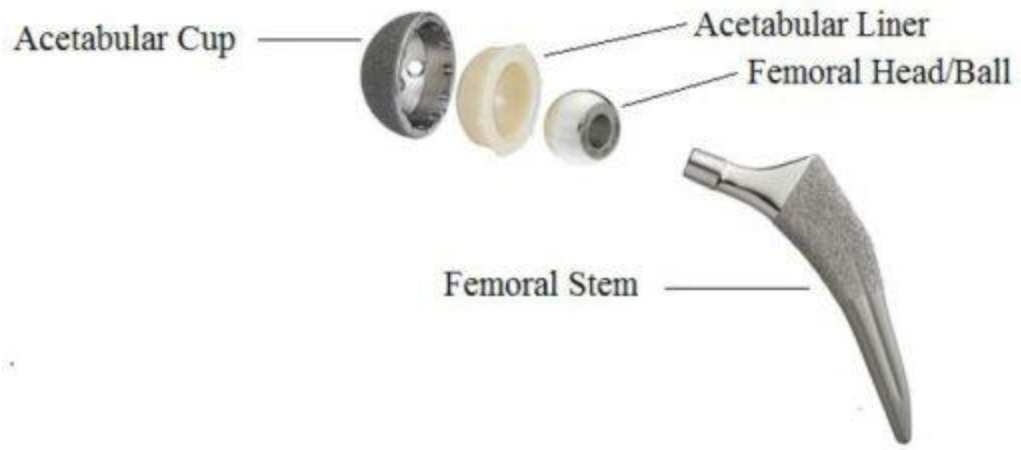
38. A hip implant should not cause metallosis to a patient in which it is implanted. Although it is hypothesized that a small amount of asymptomatic or non-toxic corrosion or metal

debris may occur with a well-functioning device, a hip implant that causes an excessive amount of fretting debris or corrosion sufficient to result in metallosis creates an unreasonable risk of injury.

39. The concern that fretting and corrosion damage could occur at the head-neck taper interface of a modular hip prosthesis was first reported in the early 1980's. Since that time, increasingly numerous studies and reports have demonstrated that a malfunctioning taper interface between a metal femoral head and metal femoral stem may be susceptible to fretting and corrosion damage resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and the need for revision surgery.

40. As total hip replacement surgery became more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear.

41. The Zimmer Hip System implanted into Plaintiff primarily consisted of four component parts: a) the M/L Taper® Hip Prosthesis Femoral Stem which was made of titanium alloy, b) the VerSys® Hip System Femoral Head which was made of cobalt/chromium alloy which was affixed to the trunnion of the femoral stem, c) the Trilogy Acetabular System Shell which was made of titanium alloy, and d) the Trilogy Acetabular System Liner which was made of highly cross-linked polyethylene. Plaintiff's Zimmer Hip System is referred to as a "metal-on-polyethylene" bearing system. An image of this type of hip system is depicted below:



42. In designing the Zimmer Hip System, Zimmer knew that the use of dissimilar metal alloys as well as taper size and geometry, trunnion surface finish, and flexural rigidity contribute to causing fretting and corrosion at the femoral head-femoral stem taper interface.

43. Mechanically assisted crevice corrosion ("MACC") has been identified as a cause for symptomatic implant failure in metal-on-polyethylene hip devices. MACC produces cobalt and chromium ions, fretting byproducts and corrosive debris that can lead to adverse local tissue reaction.

44. Adverse local tissue reaction, also referred to as aseptic lymphocyte dominated vasculitis-associated lesions ("ALVAL"), represents a distinctive periprosthetic inflammatory reaction accompanied by extensive necrosis in the soft tissue-envelope of the hip. Early detection of adverse local tissue reaction is important because as time from onset of MACC to revision surgery increases, tissue damage may worsen.

D. <u>The Design and Manufacture of the Zimmer Hip System</u>

45. Upon information and belief, Zimmer has never conducted a clinical trial on the M/L Taper® Hip Prosthesis Femoral Stem.

46. Upon information and belief, Zimmer has never conducted a clinical trial on the VerSys® Hip System Femoral Head.

47. Had Defendants conducted clinical trials of the Zimmer Hip System before the device was first released on the market, they would have discovered at that time the propensity of the device to undergo significant fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurological (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications.

48. At all times relevant to this action, Defendants were aware of the problems with the Zimmer Hip System's design and its propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper interface resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurologuical (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications. Nonetheless, Defendants still did not adequately warn patients, the medical community, or the public about these risks, and continued and continue to present day to promote, market, sell and defend the Zimmer Hip System.

49. At all times relevant to this action, Defendants failed to recognize the defects in the Zimmer Hip System due to poor and inadequate quality assurance procedures, including the failure of Zimmer to implement appropriate physical, manual, x-ray, microscopic and other

inspections of the Zimmer Hip System. Zimmer also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring and quality assessments to ensure the safety of the Zimmer Hip System.

50. At the time the Zimmer Hip System was manufactured and sold to patients, including Plaintiff, the device was defectively manufactured and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to risks of injury.

51. At all times relevant to this action, Zimmer's inadequate manufacturing processes led to material flaws in the quality systems at its manufacturing facilities including but not limited to Zimmer's manufacturing facility located in Ponce, Puerto Rico.

52. During the course of manufacturing the Zimmer Hip System, Defendants failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including corrosion fatigue or other wear testing, on components, subassemblies and/or the finished Zimmer Hip System;

b. failing to test an adequate number of sample devices on an ongoing basis;

c. failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. failing to identify and/or note the significance of any testing that resulted in failure of the Zimmer Hip System;

e. failing to take corrective actions to eliminate or minimize further failures of the Zimmer Hip System;

f. failing to adequately explain performance specifications for the

components, subassemblies, and finished Zimmer Hip System;

g. failing to adequately explain or justify all test conditions and acceptance criteria for the Zimmer Hip System;

h. failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and

i. by failing to perform adequate quality assurance testing before and after sterilization.

53. At all times relevant to this action, Zimmer failed to perform adequate testing of the Zimmer Hip System, including its components and subassemblies, to ensure that the Zimmer Hip System functioned properly during and after implantation.

54. Upon information and belief, Zimmer never conducted Spectrum Accelerated Corrosion Fatigue ("SACF") Testing on the femoral head-stem juncture of the Zimmer Hip System at any time before Plaintiff's revision surgery on February 10, 2016.

55. Upon information and belief, Zimmer never conducted Spectrum Accelerated Corrosion Fatigue ("SACF") Testing on the femoral head-stem juncture of the Zimmer Hip System at any time after Plaintiff's revision surgery on February 10, 2016.

56. As a result of these manufacturing and quality control problems associated with the manufacture of the Zimmer Hip System, the device was inadequately and defectively manufactured making it adulterated, and outside of the specifications expressly approved by the FDA.

57. On or before the date of Plaintiff's initial hip surgery, Defendants knew or should have known that the Zimmer Hip System was failing and causing serious complications after implantation in many patients. Such complications included, but were not limited to, elevated

serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurological (fatigue, weakness, poor coordination, cognitive dysfunction depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications. Defendants, however, actively concealed the true information and spread false information through, among other things, marketing and promotional materials, advertisements, and communications and meetings with orthopedic surgeons and other healthcare providers.

58. Before the date of Plaintiff's initial hip replacement surgery, Defendants knew or should have known that the Zimmer Hip System was defective and unreasonably dangerous to patients and that the product had an unacceptable failure and complication rate.

59. Defendants had legal obligations to stop promoting, marketing, selling, distributing. and defending the Zimmer Hip System. Defendants should have instead notified physicians who had implanted the Zimmer Hip System of the device's propensity for fretting and corrosion at the femoral head-stem taper interface, and for some patients to develop extremely adverse reactions to the high level of metal debris generated by wear of the device. Defendants should have attempted to convey this same information to patients who had been implanted with the Zimmer Hip System. Nonetheless, Defendants did not notify doctors or patients of the risks the Zimmer Hip System presented. Instead, Defendants concealed this material information, while continuing to market, promote, distribute, sell, and defend the Zimmer Hip System.

60. The Zimmer Hip System is not the first hip device manufactured by Defendants that has experienced complications at a metal-on-metal juncture. On July 22, 2008, Zimmer initiated a voluntary suspension of the Durom Cup from marketing and distribution in the United

States. The Durom Cup consisted of an acetabular cup made of titanium, a femoral head made of cobalt/chromium and a femoral stem made of titanium. Zimmer announced that the company was taking this "voluntary action to address its concerns regarding reports of cup loosening and revisions of the acetabular component used in total hip replacement procedures."

61. On February 4, 2013, Zimmer instituted a worldwide recall of the Trilogy Acetabular Cup including the acetabular cup implanted in Plaintiff. Zimmer's recall notice indicated that recall was due to some units of Trilogy Acetabular Cups manufactured since March 2009 falling below the lower range of pore size specification.

62. On February 20, 2014, Zimmer instituted a worldwide recall of the VerSys Head including the femoral head implanted in Plaintiff. Zimmer's recall notice indicated that packaging operations conducted in the company's manufacturing facility in Ponce, Puerto Rico were not properly validated.

63. The problems with the Zimmer Hip System are similar in nature to the issues that gave rise to Stryker Orthopedics' recent recall of the LFIT® Anatomic CoCr V40™ Femoral Heads on August 29, 2016. Both the LFIT® Anatomic CoCr V40™ Femoral Head and the VerSys Femoral Head are made of cobalt-chromium and both are mated with metal alloy stems. Stryker's Urgent Medical Device Recall Notification states that the company initiated the worldwide recall after receiving higher than expected complaints of "taper lock failure" which could result in numerous potential hazards including but not limited to excessive metal debris, excessive wear debris, disassociation of the femoral head from the hip stem and fractured hip stem trunnion leading to adverse local tissue reaction, implant loosening, loss of mobility, and pain requiring revision surgery.

64. On or about September 23, 2016, Zimmer filed a new 510(k) notification with the

FDA for the M/L Taper femoral stem (K161830). According to Zimmer's 510(k) Summary, several changes were made to how the M/L Taper femoral stem is manufactured including:

a. using a forge blank instead of a wrought blank;

b. using mass disc finishing in addition to hand polishing; and

c. a change to the laser etch type and location.

65. Upon information and belief, some or all of these manufacturing changes were made in order to address and improve the fretting and corrosion properties of the M/L Taper femoral stem when mated with the VerSys femoral head.

66. Approximately one month later on October 26, 2016, the FDA cleared the device for marketing and sale in the United States.

SPECIFIC FACTUAL ALLEGATIONS

67. On August 28, 2009, Plaintiff underwent a RIGHT total hip replacement at Spectrum Blodgett Hospital in Grand Rapids, Michigan. The surgery was performed by Dr. Gregory J. Golladay, M.D.

68. During the procedure, a Zimmer Hip System was implanted utilizing the following components:

a. VerSys® Hip System Femoral Head, 12/14 Taper, 32 mm diameter, +0 mm neck length, ("VerSys Head");
b. M/L Taper Hip Prosthesis Femoral Stem, Press-Fit, Plasma Sprayed, 12/14 Neck Taper, Size 11, Lot No. 61208800, Ref. No. 7711-11 ("M/L Taper Stem");
c. Trilogy Acetabular System Shell with Cluster Holes, Porous, 58 mm O.D., Lot No. 61260634, Ref. No. 6200-58-22 ("Trilogy Acetabular Cup");
d. Trilogy Acetabular System Liner, Standard, Longevity Crosslinked Polyethylene, 32 mm I.D., Lot No. 61204724, Ref. No. 6305-58-32; and
e. Bone Screw, Self-Tapping, 6.5 mm, 30 mm Length, Lot No. 61265375, Ref. No. 6250-65-30.

69. The VerSys Head is made of cobalt and chromium alloy.

70. The M/L Taper Stem is made of titanium (Ti6Al4V) and is circumferentially

porous-coated with titanium alloy plasma spray over the proximal body region. The M/L Taper Stem is a flat, collarless, modular femoral stem with a proximal to distal taper in the mediolateral plane. The M/L Taper is designed for cementless fixation.

71. Initially, Plaintiff did well post-operatively. Subsequently, she suffered five dislocations, the most recent being in January 2016, with minimal trauma. X-Rays demonstrated well-positioned and well-fixed implants.

72. On February 10, 2016, Plaintiff underwent a right hip revision surgery and radical debridement of a pseudotumor. The procedure was performed by Thomas A. Malvitz, M.D. at Spectrum Blodgett Hospital in Grand Rapids, Michigan.

73. Intraoperatively, Dr. Malvitz observed, among other things: (1) a membrane diffusely about the entirety of the anterior aspect of the hip consistent with a pseudotumor; (2) exuberant amount of clear, slightly purulent material; (3) loss of soft tissue posteriorly and anteriorly, as well as stripping up the lateral acetabulum and posteriorly around the acetabulum; and, (4) evidence of black material over the Morse taper consistent with corrosion.

THE FEDERAL REQUIREMENTS

74. The Medical Device Amendments of 1976 ("MDA") to the Food Device Cosmetic Act ("FDCA") established the current regulatory framework for medical devices.

75. The MDA, in theory, requires medical devices like the Zimmer Hip System to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

76. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or

should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

77. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

78. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – is not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976).

79. This exception to premarket approval is known as "510(k) clearance" which only requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

80. All the component parts comprising Plaintiff's Zimmer Hip System were cleared for marketing by the FDA pursuant to 510(k) of the MDA or were marketed without receiving either 510(k) clearance or pre-market approval by the FDA.

81. According to the U.S. Supreme Court in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 346 (2001), the Supreme Court explained that demonstrating that a device qualifies for

this, known as the "§ 510(k) process," means that: "[s]ection 510(k) submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use,' 21 CFR § 807.87(e) (2000); and must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "any additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," § 807.87(l).

82. The FDCA requires cleared medical devices to be demonstrated to be safe and effective for each intended use.[1] Not only is the medical device itself part of the 510(k) process, but so is the labeling and packaging that comes with it.

83. A manufacturer is required to give adequate directions for the use of a medical device such that a "layman can use a device safely and for the purposes for which it is intended"[2], and conform to section 801.15 requirements governing the appearance of the label.

84. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling.[3] False and misleading labeling is considered misbranding[4], which is prohibited.[5]

[1] 21 U.S.C. § 360e(c)(2)(A)(iv) (2012).
[2] 21 C.F.R. § 810.5 (2012).
[3] 21 U.S.C. § 321(n) (2012).
[4] 21 U.S.C. § 321(a), q(1) (2012).
[5] 21 U.S.C. § 331(b).

85. The distribution of a "misbranded" medical device is prohibited pursuant to 21 U.S.C. §§ 331(a), (k) (2012) and 21 U.S.C. § 352(f) (2012).

86. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written including adverse events when the manufacturer has failed to disclose those adverse events to the FDA. Therefore, the labeling becomes inadequate and the product is misbranded.

87. Federal law requires a manufacturer to ensure that any warranty statements it voluntary makes are truthful, accurate, not misleading, and consistent with applicable federal and state law.[6]

88. Under the FDCA, medical device manufacturers are prohibited from introducing the adulteration or misbranding of any medical device into interstate commerce.[7]

A. The FDA, By Its Regulations and 510(k) Clearance Process, Prohibits Misleading or False Promotional and Marketing Activities

89. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices.[8]

90. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed misleading if they omit or ignore certain information about the product's risks

91. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular. Labeling or advertising may be considered misleading if it fails to

[6] 21 U.S.C. § 331(b) (effective 2013).
[7] *Id.*
[8] See 21 U.S.C. § 352(a), (n), (q) & (4) (2012).

reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece.[9]

B. After a Medical Device is Cleared via the 510(k) Process, a Device Manufacturer Still Has Requirements, Including General Reporting Requirements, to the FDA Mandated by Federal Regulations

92. A manufacturer's obligations do not end with 510(k) clearance by the FDA. Even after clearance, manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

a. May have caused or contributed to death or serious injury; or

b. Has malfunctioned and this device or a similar device [likewise marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.[10]

93. These reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession.

94. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and, must evaluate the cause of the adverse event.[11]

95. Manufacturers are required to make periodic reports to the FDA regarding cleared devices, such reports to include summaries of:

a. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant; and,

[9] 21 U.S.C. § 321(n) (2012); 21 C.F.R. §§ 1.21, 202.1(e)(5)(iii) (2012).
[10] 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012).
[11] 21 C.F.R. § 803.50(b)(3).

b. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant.[12]

96. The medical device manufacturer has a continuing duty to monitor the product after FDA clearance and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product.

97. The manufacturer is obligated to inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know.[13]

98. The FDA can revoke its clearance based on these post-approval reports.[14]

99. The manufacturer must establish internal procedures for reviewing complaints and adverse event reports.[15] Medical device manufacturers are required by federal regulation to "establish and maintain" an adverse event database.[16] Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device.[17]

100. Federal law also mandates that the FDA establish regulations requiring manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health.[18]

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[12] 21 C.F.R. § 814.84(b)(2) (2012).
[13] *Id.*
[14] 21 U.S.C. §§ 360(e)(1), 360(h)(e) (2012).
[15] 21 C.F.R. § 820.198(a) (2012).
[16] 21 C.F.R. § 803.1(a) (2012).
[17] 21 C.F.R. § 803.52 (2012).
[18] 21 U.S.C. § 360(i).

101. Manufacturers must disclose any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events.[19]

102. Device manufacturers must report promptly to FDA any device corrections and removals, and, maintain records of device corrections and removals.

103. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and, provide a copy of all communications regarding the correction or removal.[20]

104. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses.

105. Manufacturers must also meet quality standards in manufacture and production of the devices.

[19] See 21 C.F.R. § 806 (2012).
[20] See 21 C.F.R. § 806 (2012).

106. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions; investigate the cause of nonconforming products; and, take corrective action to prevent recurrence.

107. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary.

108. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance.

109. Zimmer failed to comply with several of these requirements which led to the devices being on the market for use by Plaintiff's doctor.

110. Zimmer failed to comply with many of these above-mentioned FDA regulations and requirements.

111. Zimmer failed to report adverse events timely to the FDA.

112. Zimmer failed to investigate and correct problems with the Zimmer Hip System.

C. After Clearance of a Medical Device, The FDA, By Its Regulations and PMA Process, Requires A Manufacturer To Follow Good Manufacturing Practices

113. Under 21 C.F.R. § 820.1(a) (2012) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). This part establishes basic requirements applicable to manufacturers of finished medical devices.

114. 21 C.F.R. § 820.5 (2012) "Quality Systems," the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

115. 21 C.F.R. § 820.3(z)(2) (2012) "Design validation," means the manufacturer must establish objective evidence that device specifications conform with user needs and intended use(s)."

116. 21 C.F.R. § 820.22 (2012): "Quality Audit" states: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."

117. 21 C.F.R. § 820.160(a) (2012): "Distribution" states: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution."

118. 21 C.F.R. § 820.170(a) (2012): "Installation" states: "Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device."

119. 21 C.F.R. § 803 (2012), states: "Manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting ("MDR")

submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use."

120. 21 C.F.R. § 820.100 (2012) "Corrective and Preventive Action" states: (a) [e]ach manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; an

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

D. Zimmer's Conduct in Violation of the FDCA

121. Zimmer violated these FDCA statutes and accompanying regulations by:

a. falsely and misleadingly promoting the Zimmer Hip System;

b. failing to report adverse events to the FDA;

c. failing to timely conduct failure investigations and analysis;

d. failing to timely report any and all information concerning product failures and corrections;

e. failing to timely and fully inform FDA of unanticipated adverse effects, including device corrosion, increases in the incidence of adverse effects, and device failures

necessitating a labeling, manufacturing or device modification;

f. failing to conduct necessary design validation;

g. selling and distributing a misbranded and adulterated product through interstate commerce; and

h. failing to immediately disclose the metallosis risk from the fretting and corroding failure of the Zimmer Hip System after implantation in patients.

122. Zimmer's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth herein.

123. Zimmer's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the use of the Zimmer Hip System in Plaintiff and Zimmer's misconduct in this regard thus directly caused or contributed to Plaintiff's injuries and damages.

FIRST CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT

124. Plaintiff hereby incorporates by reference paragraphs, 1 – 123, of this Complaint as if fully set forth herein and further alleges as follows:

125. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

126. The Zimmer Hip System was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because the risks were

outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Zimmer Hip System was in a condition not suitable for its proper and intended use.

127. At all times herein mentioned, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to the following respects:

a. that the Zimmer Hip System has the propensity to undergo fretting and corrosion at the femoral head-stem taper juncture causing serious complications in patients;

b. that the Zimmer Hip System differed from the manufacturer's intended design or specifications, or from other typical units of the same product line;

b. that the Defendants failed to conduct adequate mechanical testing, including corrosion fatigue or other wear testing, on components, subassemblies and/or the finished Zimmer Hip System;

c. that Defendants failed to test an adequate number of sample devices on an ongoing basis;

c. that Defendants failed to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

d. that Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Zimmer Hip System;

e. that Defendants failed to take corrective actions to eliminate or minimize further failures of the Zimmer Hip System;

f. that Defendants failed to adequately explain performance specifications for the components, subassemblies, and/or the finished Zimmer Hip System;

g. that Defendants failed to adequately explain or justify all test conditions and acceptance criteria for the Zimmer Hip System;

h. that Defendants failed to perform adequate testing in an environment that adequately simulated in vivo conditions;

i. that Defendants failed to perform adequate testing of the Zimmer Hip System, including its components and subassemblies, to ensure that the Zimmer Hip System functioned properly during and after implantation;

j. that Defendants failed to perform adequate testing on the specific Zimmer Hip System components which were intended to be sold to and implanted with consumers including Plaintiff and instead conducted testing with "dummy" parts designed and intended only for manufacturer testing purposes; and

k. that Defendants failed to perform adequate quality assurance testing and validation before and after sterilization.

128. Plaintiff's physicians employed the Zimmer Hip System in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

129. The Zimmer Hip System as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

130. As alleged herein, Defendants knew and had reason to know that the Zimmer Hip System caused increased risks of harm to the Plaintiff and other consumers. Defendants consciously disregarded these increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer Hip System; and continuing to market, promote, sell and defend the device.

131. As alleged herein, the defects in manufacture of the Zimmer Hip System were a substantial factor in causing Plaintiff's injuries.

132. As a direct, proximate and legal consequence of Defendants' wrongful conduct as

described herein, including the defective manufacture of the Zimmer Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; potential for recurrent dislocation, metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SECOND CAUSE OF ACTION
STRICT LIABILITY – DESIGN DEFECT

133. Plaintiff hereby incorporates by reference paragraphs 1 – 123 of this Complaint as if fully set forth herein and further alleges as follows:

134. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

135. The Zimmer Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the risks were outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did

Plaintiff have reason to believe that the Zimmer Hip System was in a condition not suitable for its proper and intended use.

136. The Zimmer Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

137. At all times relevant to this action, the Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design.

138. The Zimmer Hip System implanted in Plaintiff was defective in design in all or some of, and without limitation, the following respects:

a. The device employs a femoral stem-head taper juncture which due to its geometry is misfit and has the propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients;

b. The device employs a femoral head which by virtue of its size, shape, length, diameter, material, and/or bore taper angle has the propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients; and,

c. The device employs a femoral stem which by virtue of its size, shape, length, offset, material, elasticity, flexural rigidity and/or surface area has the propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients.

139. Plaintiff's physicians employed the Zimmer Hip System in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

140. The Zimmer Hip System as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or

sold by Defendants reached Plaintiff without substantial change in its condition.

141. As alleged herein, Defendants knew and had reason to know that the Zimmer Hip System caused increased risks of harm to the Plaintiff and other consumers. Defendants consciously disregarded these increased risks of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer Hip System; and continuing to market, promote, sell and defend the Zimmer Hip System.

142. As alleged herein, the defects in design of the Zimmer Hip System were a substantial factor in causing Plaintiff's injuries.

143. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable and, in fact, were being sold and marketed by Defendants at the time Defendants sold the Zimmer Hip System to Plaintiff.

144. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including the defective design of the Zimmer Hip System, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; recurrent dislocation, soft tissue damage; adverse local tissue reaction; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be

proven at trial.

THIRD CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

145. Plaintiff hereby incorporates by reference paragraphs 1 – 123 of this Complaint as if fully set forth herein and further alleges as follows:

146. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

147. The Zimmer Hip System was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the risks were outweighed by any utility of the design of the device and because the device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Zimmer Hip System was in a condition not suitable for its proper and intended use.

148. The Zimmer Hip System was defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

149. The Zimmer Hip System posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of the Zimmer Hip System to Plaintiff.

150. Defendants knew or should have known of the defective condition, dangerous characteristics, and risks associated with the Zimmer Hip System as alleged herein.

151. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer Hip System; and continuing to market, promote, sell and defend the Zimmer Hip System.

152. The Zimmer Hip System that was manufactured, distributed, and sold by the Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

153. Such ordinary consumers, including Plaintiff, would not and could not have recognized or discovered the potential risks and side effects of the Zimmer Hip System as alleged herein.

154. The instructions for use, directions and warnings provided by Defendants with the Zimmer Hip System failed to adequately convey the potential risks and side effects of the Zimmer Hip System and the dangerous propensities of the device, which risks were known or were reasonably scientifically knowable to Defendants.

155. The Zimmer Hip System was expected to and did reach Plaintiff and his orthopedic surgeon without substantial change in its condition as manufactured, distributed, and sold by Defendants.

156. Plaintiff's orthopedic surgeon used the Zimmer Hip System in the manner in which it was intended to be used, making such use reasonably foreseeable to Defendants.

157. The lack of adequate instructions for use, directions and warnings with the Zimmer Hip System prior to, on, and after the dates of Plaintiff's initial hip surgery were a substantial

factor in causing Plaintiff's injuries, losses and damages as alleged herein.

158. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable and, in fact, were being sold and marketed by Defendants at the time Defendants sold the Zimmer Hip System to Plaintiff.

159. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' lack of sufficient instructions or warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; recurrent dislocation; metallosis; soft tissue damage; adverse local tissue reaction; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; lost wages; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
NEGLIGENCE – DESIGN, MANUFACTURE & SALE

160. Plaintiff hereby incorporates by reference paragraphs 1 – 123 of this Complaint as if fully set forth herein and further alleges as follows:

161. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion,

advertisement, marketing, distribution and sale of the Zimmer Hip System for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

162. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to exercise reasonable care and were negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Zimmer Hip System.

163. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to perform adequate evaluation and testing of the Zimmer Hip System, where such adequate evaluation and testing would have revealed the device's propensity to undergo fretting and mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients.

164. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants had received complaints from healthcare providers that the Zimmer Hip System caused serious complications including but not limited to fretting and mechanically assisted crevice corrosion at the femoral head-stem taper juncture, but Defendants nonetheless consciously decided not to perform any further testing on the Zimmer Hip System; investigate the root cause of these complications; suspend sales and distribution of the device; or warn physicians and patients of the propensity of the Zimmer Hip System to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients.

165. Defendants' failure to exercise reasonable care in the design, testing, distribution, manufacture, advertising, sales, and marketing prior to, on, and after the dates of Plaintiff's initial hip surgery was a substantial factor in causing Plaintiffs' injuries, losses, and damages, as

alleged herein.

166. As alleged herein, Defendants knew and had reason to know that the Zimmer Hip System caused increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer Hip System; and continuing to market, promote, sell and defend the Zimmer Hip System.

167. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' failure to exercise reasonable care as described herein, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; recurrent dislocations; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
NEGLIGENCE – FAILURE TO WARN

168. Plaintiff hereby incorporates by reference paragraphs 1 – 123 of this Complaint as if fully set forth herein and further alleges as follows:

169. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all relevant times, Defendants tested, studied, researched, designed, formulated, manufactured, inspected,

labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System for implantation into consumers, such as Plaintiff, by physicians and orthopedic surgeons in the United States.

170. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants knew or should have known that the Zimmer Hip System was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner. Such danger included the propensity of the Zimmer Hip System's to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients.

171. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants knew or reasonably should have known that the users of the device, including Plaintiff, would not realize the dangers presented by the device.

172. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to adequately warn of the dangers presented by the device and/or failed to instruct on the safe use of the device. Such failures to warn and/or instruct included, but were not limited to failing to advise of the known or knowable risks, dangers, and side effects associated with the use of the Zimmer Hip System; failing to properly advise of the means and methods available for the elimination of the risks, dangers, and side effects associated with the Zimmer Hip System; failing to warn physicians about the risks, dangers, and side effects associated with the Zimmer Hip System, including the propensity of the Zimmer Hip System's to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients; and failing to warn consumers about the risks, dangers, and side effects associated with the Zimmer Hip System, including the propensity of the Zimmer Hip System to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-

stem taper juncture causing serious complications in patients.

173. Reasonable manufacturers and distributors, under the same or similar circumstances prior to, on, and after the dates of Plaintiff's initial hip surgery, would have adequately warned of the dangers presented by the Zimmer Hip System, or provided adequate instructions for the safe use of the Zimmer Hip System.

174. Prior to the dates of Plaintiff's initial hip surgery, the Zimmer Hip System had already caused numerous known reports of fretting and/or mechanically assisted crevice corrosion at the taper juncture between the femoral head and femoral stem. Defendants consciously decided neither to warn physicians or patients of the Zimmer Hip System's increased propensity to cause these serious complications, nor of the signs and symptoms of these complications.

175. Defendants' negligent failure to warn Plaintiff, Plaintiff's orthopedic surgeon or Plaintiff's other healthcare providers prior to, on, and after the dates of Plaintiff's initial hip surgery was a substantial factor in causing Plaintiff's injuries, losses and damages as described herein.

176. As alleged above, Defendants knew and had reason to know that the Zimmer Hip System caused an increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer Hip System; and continuing to market, promote, sell and defend the Zimmer Hip System.

177. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent failure to warn, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain

and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

178. Plaintiff hereby incorporates by reference paragraphs 1- 123 of this Complaint as if fully set forth herein and further alleges as follows:

179. Defendants impliedly warranted that the Zimmer Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold to Plaintiff, was merchantable and fit and safe for ordinary use.

180. Defendants further impliedly warranted that the Zimmer Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold, was fit for the particular purposes for which it was intended and was sold.

181. Contrary to these implied warranties, the Zimmer Hip System was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the particular purpose for which it was sold.

182. As a direct, proximate and legal consequence of Defendants' wrongful conduct as

described herein, including Defendants' breach of implied warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

SEVENTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTIES

183. Plaintiff hereby incorporates by reference paragraphs 1 – 123 of this Complaint as if fully set forth herein and further alleges as follows:

184. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, product information, instructions for use, sales and marketing materials, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the Zimmer Hip System was safe, effective, fit and proper for its intended use.

185. In allowing the implantation of the Zimmer Hip System, Plaintiff and Plaintiff's physicians relied on the skill, judgment, representations, and the express warranties of Defendants.

186. These warranties and representations were false in that the Zimmer Hip System was not safe and was unfit for the uses for which it was intended.

187. Through the sale of the Zimmer Hip System, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

188. Defendants breached their warranty of the mechanical soundness of the Zimmer Hip System by continuing sales and marketing campaigns highlighting the safety and efficacy of the device, when Defendants knew of the defects, risk and propensity of the device to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients.

189. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' breach of express warranties, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

190. Plaintiff hereby incorporates by reference paragraphs 1 – 123 of this Complaint as if fully set forth herein and further alleges as follows:

191. At the time Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or

sold the Zimmer Hip System to Plaintiff, Defendants knew or should have known of the use for which the device was intended and the serious risks and dangers associated with such use of the Zimmer Hip System.

192. Defendants owed a duty to orthopedic surgeons, other healthcare providers and to consumers of the Zimmer Hip System, including Plaintiff, to accurately and truthfully represent the risks of Zimmer Hip System.

193. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the Zimmer Hip System, which Defendants knew or in the exercise of diligence should have known.

194. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the Zimmer Hip System was safe, had an excellent track record and low failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Zimmer Hip System in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Zimmer Hip System. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons.

195. Despite their knowledge of serious problems with the Zimmer Hip System, Defendants urged their sales representatives to continue marketing the Zimmer Hip System, and distributed medical literature and other communications to surgeons in an effort to mislead them and the general public about the risks associated with the Zimmer Hip System.

196. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' negligent misrepresentations, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

NINTH CAUSE OF ACTION
INTENTIONAL MISREPRESENTATION

197. Plaintiff hereby incorporates by reference paragraphs 1 – 123 of this Complaint as if fully set forth herein and further alleges as follows:

198. Defendants, having undertaken to test, study, research, design, formulate, manufacture, inspect, label, package, promote, advertise, market, distribute and sell the Zimmer Hip System, owed a duty to provide accurate and complete information to Plaintiff, Plaintiff's orthopedic surgeon, and the public regarding the safety and efficacy of the Zimmer Hip System.

199. However, Defendants misled Plaintiff, Plaintiff's orthopedic surgeon, and the public into believing that the Zimmer Hip System was safe and effective for use in total hip replacement surgery; engaged in deceptive, misleading and unconscionable promotional, marketing and sales tactics to convince orthopedic surgeons and patients to use the Zimmer Hip System, even though Defendants knew or should have known that the Zimmer Hip System was

unreasonably dangerous as alleged herein. Defendants also failed to warn orthopedic surgeons and the public about the serious risks associated with the use of the Zimmer Hip System.

200. Defendants' advertising campaigns, marketing materials and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Zimmer Hip System was safe for human use and had no unacceptable risks.

201. Defendants purposefully concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the Zimmer Hip System. Defendants, through sales, marketing and promotional practices as well as through the publication of medical literature, deceived orthopedic surgeons, Plaintiff, other patients, and the public. Defendants falsely and deceptively kept relevant information from orthopedic surgeons, the FDA and the public, including Plaintiff, regarding the safety of the Zimmer Hip System.

202. Defendants expressly denied that the Zimmer Hip System created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence regarding the increased likelihood of injury from the Zimmer Hip System.

203. Defendants did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, orthopedic surgeons, Plaintiff, and the public, the truth regarding Zimmer Hip System's failures for years, all the while undertaking sales, marketing and promotional campaigns to sell the Zimmer Hip System. Defendants received reports of the Zimmer Hip System defects from various sources, including those alleged herein, and intentionally withheld this information, while continuing to sell the Zimmer Hip System for implantation in patients such as Plaintiff.

204. Further, even as Defendants disclosed some information regarding the Zimmer Hip

System's defects, the disclosures were incomplete and misleading.

205. Through their wrongful conduct, Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Zimmer Hip System. Defendants failed to fully inform orthopedic surgeons, Plaintiff, other patients and the public of the true risks associated with the Zimmer Hip System, defects that were known to Defendants, and continued to assure orthopedic surgeons and patients that the Zimmer Hip System was safe and effective for the purpose of continuing to derive substantial profits from the sale of the Zimmer Hip System.

206. Through their advertising campaigns, sales and marketing materials and promotional items, Defendants falsely and deceptively misrepresented and omitted a number of material facts regarding the Zimmer Hip System.

207. Defendants possessed evidence demonstrating the Zimmer Hip System caused serious injuries. Nevertheless, Defendants continued to market the Zimmer Hip System by providing false and misleading information with regard to the device's safety and efficacy to Plaintiff, and plaintiff's orthopedic surgeon.

208. Among Defendants' numerous misrepresentations and misleading omissions to Plaintiff, plaintiff's orthopedic surgeon and the public were Defendants' assurances that the Zimmer Hip System was safe and had a low failure rate. Defendants stated or implied to orthopedic surgeons that any problem with the Zimmer Hip System in a particular patient was attributable to "surgical technique" or patient factors such as body mass index, bone composition, and post-implantation activity level. Defendants made such statements even after they became aware of numerous and serious complications with the Zimmer Hip System. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious

complications and other bad data during their meetings with orthopedic surgeons.

209. Despite their knowledge of the risks with the Zimmer Hip System, Defendants urged their sales representatives to continue marketing the Zimmer Hip System and distributed medical literature and other communications to orthopedic surgeons in an effort to mislead them and the public about the serious risks associated with the use of the Zimmer Hip System.

210. Defendants engaged in all the acts and omissions alleged herein with the intent that Plaintiff's orthopedic surgeon and Plaintiff would rely on the misrepresentation, deception and concealment in deciding to implant and use the Zimmer Hip System rather than another Zimmer product or a competitors' product.

211. Plaintiff, and Plaintiff's orthopedic surgeon justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations and this reliance proximately caused Plaintiff's injuries and damages as alleged herein.

212. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, including Defendants' deceptive, misleading and unconscionable promotional and sales methods, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening, impingement and/or detachment; metallosis; soft tissue damage; adverse local tissue reaction; dislocation; infection; and other injuries presently undiagnosed, which all require ongoing medical care. As a further direct, proximate and legal consequence of the defective nature of the Zimmer Hip System, Plaintiff has sustained and will sustain future damages, including but not limited to additional revision surgeries; cost of medical care; rehabilitation; home health care; mental and emotional distress; and pain and suffering for which plaintiff is entitled to compensatory and equitable damages and

declaratory relief in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants, in an amount of damages in excess of seventy-five thousand dollars ($75,000.00), individually, jointly, severally, and in the alternative, including:

a. Awarding actual damages to Plaintiff incidental to the purchase and use of the products at issue in an amount to be determined at trial;

b. Awarding the past and future costs of treatment for Plaintiff's injuries caused by the products at issue in an amount to be determined at trial;

c. Awarding damages for Plaintiff's physical pain and suffering in an amount to be determined at trial;

d. Awarding damages for Plaintiff's mental and emotional anguish in an amount to be determined at trial;

e. Awarding damages for Plaintiff's loss of earnings and future earning capacity:

f. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present;

g. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent

instability and loss of balance, and pain and suffering;

h. Double or triple damages as allowed by law;

i. Attorneys' fees, expenses, and costs of this action;

j. Pre-judgment and post-judgment interest in the maximum amount allowed by law;

k. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues and matters so triable by jury as a matter of right.

Dated: February 2, 2019

Respectfully Submitted By:

CARLA D. AIKENS, P.C.

/s/ Carla D. Aikens
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